OMB No. 0990-0115

Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE http://www.niaid.nih.gov/contract/default.htm FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Purchase Authority: Public Law 92-218, as amended.
NOTE: The issuance of this solicitation does not commit the government to an award.

RFP Number:	***Just In Time:***	Small Bus. Set-Aside [X]Yes [ ]No 8(a) Set-Aside [ ]Yes [X]No NAICS Code: 54171 Size Standard: 500 employees	***Level of Effort:*** [ ] Yes [X] No ***Total Effort:*** [N/A]
NIH-NIAID-DAIDS-03-01	[ ] Yes [X] No		

TITLE: Reagent Resource Support For AIDS Vaccine Development

Issue Date:	***Due Date:***	***Technical Proposal Page Limits:***
MARCH 14, 2002	***Time:*** **4:00 PM, EST**	[X] Yes *(see "How to Prepare and Submit Electronic Proposals")* [ ] No

ISSUED BY:

Barbara A. Shadrick
Senior Contracting Officer
Contract Management Branch, DEA
NIAID, NIH
6700-B Rockledge Drive, Room 2230
Bethesda, MD 20892-7612

[X] ***We reserve the right to make awards without discussion.***

NO. OF AWARDS:	***PERIOD OF PERFORMANCE:***
[X] Only 1 Award [ ] Multiple Awards	7 years beginning on or about 02/14/2003

Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

POINT OF CONTACT **-- Lois Eaton** ***--COLLECT CALLS WILL NOT BE ACCEPTED--***

Telephone: ***Direct*** **301-496-0611** ***Main*** **301-496-0612**	***Fax*** **301-402-0972**	***E-Mail*** **le52u@nih.gov**

TABLE OF CONTENTS

BACKGROUND / STATEMENT OF WORK / NOTES TO OFFERORS
Background/Introduction
Reagent Resource Support For AIDS Vaccine Development
DAIDS-03-01

The Division of Acquired Immune Deficiency Syndrome (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), is committed to the development of an efficacious vaccine against HIV for worldwide use in stemming the AIDS epidemic. While industry, government, and academia have all targeted considerable resources to this end over the past 15 years, identification of an efficacious vaccine against HIV/AIDS has yet to be accomplished. A wide assortment of candidate HIV-1 vaccines has already been pursued and many have reached the stage of safety and immunogenicity testing in humans. However, only one vaccine efficacy trial has been initiated, and a second efficacy trial is unlikely to begin before 2002.

At this time the highest priority of the DAIDS is the discovery, development, and evaluation of HIV/AIDS vaccines and other prevention products. DAIDS supports research to identify vaccine strategies against HIV-induced acquired immunodeficiency syndrome (AIDS). To facilitate this research, DAIDS has long provided the research community with standardized, quality-controlled reagents through the NIH AIDS Research and Reference Reagent Program. However, large-scale preclinical and clinical vaccine research studies, such as those carried out by DAIDS-sponsored Simian Vaccine Evaluation Units (SVEUs) and the HIV Vaccine Trials Network (HVTN), require large quantities of such reagents not available through the AIDS Research and Reference Reagent Program.

Therefore, to advance the development of both vaccine and non-vaccine prevention products, DAIDS is seeking ways to generate and acquire reagents and technologies as needed for sponsored AIDS vaccine research and development projects. Many such reagents are not commercially available and require customized production and quality control. Reagents required for this research include but are not limited to viral gene products and associated peptides, adjuvants, cytokines, virus stocks, expression vectors, monoclonal and polyclonal antibodies, and sometimes unforeseen but appropriately and timely produced reagents. These reagents will be generated for evaluating vaccine safety, immunogenicity, and efficacy. DAIDS currently supports under contract a facility to produce or otherwise acquire these types of reagents for AIDS vaccine research. In addition, this Contractor has the capability to store, maintain, assure quality control and distribute large quantities of reagents. To facilitate the research and development of potential AIDS vaccines in preclinical and clinical studies, there is an essential need to continue this service.

This contract is utilized by nearly all facets of the AIDS prevention and vaccine development resources funded by DAIDS. Grantees, contractors, and other investigators regularly make requests through this DAIDS program to obtain essential reagents for their vaccine development studies. In addition, novel procedures are often developed for optimizing the production of these reagents (e.g., to achieve greater yields and higher purity). The importance of this contract initiative is well recognized, and its continuance is a vital part of the AIDS vaccine research effort. The reagents produced and procedures developed under this contract will continue to be targeted primarily for use in supporting the DAIDS-sponsored AIDS vaccine contracts that include the human HIV Vaccine Trials Network (HVTN) and HIV Vaccine Design and Development Teams (HVDDT), the Simian Vaccine Evaluation Units (SVEUs), the Primate Core Immunology Laboratory, as well as the extramural grantees and contractors supported by NIAID's HIV Vaccine Research and Development Program (HIVRAD) and Integrated Preclinical/ Clinical AIDS Vaccine Development Program (IPCAVD). Furthermore, new information developed within this reagent contract is consistently shared with the Project Officer responsible for the AIDS Research and Reference Reagent Program and reagents generated under the contract are often provided to the Research and Reference Reagent Program, thereby complementing and enhancing the quality of both programs.

Statement of Work
Reagent Resource Support For AIDS Vaccine Development
RFP DAIDS-03-01

For the recompetition of this contract, the Offeror will be expected to 1) produce (either through purchase or other means), purify, and test reagents for the DAIDS Vaccine and Prevention Research Program; these reagents include an array of viral proteins and peptides, virus stocks, monoclonal and polyclonal antibodies, topical microbicides, vaccine adjuvants and cytokines, and any additional reagents deemed necessary for the DAIDS vaccine program, 2) have capabilities for genetic cloning and sequencing, 3) be capable of producing and testing unique and customized reagents at the request of the program, including preparing and/or producing soluble proteins, expression vectors, and gene products (including experimental AIDS vaccines) under current Good Laboratory Practice (cGLP) or Good Manufacturing Practice (cGMP) as appropriate for their intended use, and preparing and/or producing these in large-scale production lots, 4) be able to analyze all acquired or generated reagents for purity and integrity, and to provide for their quality control and assurance, and 5) provide for appropriate receipt and inventory tracking, storage, maintenance and distribution of all reagents. The Contractor will be monitored by regular communications between the NIAID Project Officer and the contract Principal Investigator and through site visits by DAIDS staff. NIAID will receive written reports (quarterly updates and annual reports) as well as reports of data from individual studies in progress.

Therefore, independently, and not as an agent of the Government, the Contractor shall furnish services, qualified professional and technical personnel, material, equipment, and facilities not otherwise provided by the Government under the terms of this contract as needed to perform the work set forth below.

Specifically, the Contractor shall:

A. Acquire by purchase or other means, as specified by the Project Officer, reagents (i.e., either those commercially available or from other sources, such as from academia) to support uniform and comparable preclinical and clinical testing of both vaccine and prevention (e.g., topical microbicides) products, concepts, and strategies among the groups of investigators in Division of AIDS (DAIDS)-supported cooperative agreements, contracts and grantees. These include, but are not limited to, the DAIDS human HIV Vaccine and Prevention Trials Networks (HVTN and HPTN, respectively), the Simian Vaccine Evaluation Units (SVEUs), the Primate Core Immunology laboratory, the HIV Vaccine Design and Development Teams (HVDDTs), and the extramural grantees supported by NIAID's HIV Vaccine Research and Development (HIVRAD) programs. These latter programs include the Integrated Preclinical/Clinical AIDS Vaccine Development Program (IPCAVD) and the Innovation Grant Program for AIDS Vaccine Development. Furthermore, new information and reagents developed within this reagent contract is to be shared with the Project Officers responsible for the AIDS Research and Reference Reagent Program.

1. Viral gene products

   As specified by or as designated by the Project Officer, obtain by purchase or other arrangement and then characterize individual viral gene products of HIV, SIV, SHIV or related human and nonhuman primate lentiviruses, in each contract year, as follows:

   a) Acquire a particular gene product from a supplier in approximately 1-10 mg lots, as specified by the Project Officer, for analysis by the Contractor under paragraph c), below. Gene products of HIV, SIV, SHIV and other lentiviruses shall include, but not necessarily be limited to: env gene products from immunologically distinct field and laboratory isolates of HIV-1 (e.g., HIV-1IIIB, HIV-1SF2, HIV-1MN), env gene products from immunologically distinct strains of SIV or SHIV (e.g., SIVmac, SIVmne, SHIV 89.6P), and gag, pol, and regulatory gene (e.g. rev, tat, or nef) products from HIV, SIV and/or SHIV.

   b) Analyze each gene product lot for protein concentration, total protein content, reactivity with antigen-specific antiserum, purity and protein integrity, and any identifiable contaminants. For analysis of glycoproteins, the Contractor shall perform digestions with various glycosidases followed by electrophoretic analysis in order to characterize the carbohydrate component. Provide to the Project Officer a data sheet containing this information upon completion of characterization of each product.

c) Acquire larger lots (10-100 mg or more) of the tested product lots for subsequent distribution as described under paragraph F below.

2. Preclinical/Clinical DNA Preparation

As instructed by the Project Officer, receive or procure novel vaccine DNA preparations (e.g., recombinant plasmids) primarily under current Good Laboratory Practice (cGLP) standards for DAIDS-sponsored nonhuman primate studies, but also for DAIDS-sponsored clinical studies under Good Manufacturing Practice (cGMP) standards. Evaluate these reagents in standardized quality control and quality assurance tests for identity, size, appearance, purity, and sterility.

3. Adjuvants, immunomodulators, vaccine delivery systems

Receive or procure novel vaccine adjuvants, immunomodulators, and vaccine delivery systems as instructed by the Project Officer. Evaluate these reagents in standardized safety and immunogenicity assays using HIV, SIV, or SHIV antigens as instructed by the Project Officer. Perform stability studies on selected vaccine/adjuvant formulations to support clinical (e.g., within the HVTN) or preclinical DAIDS-supported vaccine trials.

4. Reagents

Acquire reagents used to evaluate AIDS vaccine safety and immunogenicity (which may include, but are not limited to, reagents for use in lymphoproliferation, ELISPOT, and intracellular cytokine assays, CTL activity assessments, and antibody binding/virus neutralizing assays). In addition, acquire reagents needed for evaluation of the safety and potential efficacy of topical microbicides, and reagents and assays for evaluating the biological effects of these prevention formulations. The Contractor shall confirm the identity, purity, and stability of the various reagents.

B. As specified by the Project Officer, generate or acquire in sufficient quantities, custom reagents not otherwise available for AIDS vaccine and topical microbicide research and development to support uniform and comparable testing of these products, concepts, and strategies among the groups of investigators supported by DAIDS in this activity (as stated above in paragraph A). This activity will include preparing and/or producing soluble proteins, expression vectors, and gene products (including experimental AIDS vaccines) under cGLP or cGMP as appropriate for their intended use, and preparing and/or producing these in large-scale production lots. The Project Officer may direct that reagents developed under this contract be provided to the NIH AIDS Research and Reference Reagent Program repository.

1. Virus Stocks

Obtain field and laboratory isolates of HIV-1 or other related retroviruses from various sources (e.g., the World Health Organization or HVTN clinical investigators). Expand virus isolates in peripheral blood mononuclear cell (PBMC) and T lymphocyte (T cell) cell lines for use in in vitro and in vivo neutralization assays. Maintain panels of PBMC- and T-cell-grown field isolate stocks for distribution to DAIDS-supported researchers.

2. Genes for cloning into expression vectors

a) Prepare or acquire all necessary materials for cloning genes into suitable cloning vectors.

b) Grow, evaluate, and characterize genetically modified cloning vectors.

This activity may include genetic sequencing of gene inserts and additional similarly detailed characterizations. Evaluate DNA suitable for further cloning or subcloning.

c) Synthesize or construct primers (e.g., those suitable for polymerase chain reaction amplifications) and specific nucleic acid sequences.

3. Prepare expression vectors and produce gene products

a) Clone genes, identified by the Project Officer, into appropriate expression vectors. The selection and source of the DNA and vector used for cloning will be specified by the Project Officer and shall be acquired or produced by the Contractor.

b) Produce and purify specific gene products from expression clones produced by the Contractor or provided by the Project Officer. The Contractor shall confirm the identity and purity of the protein product.

4. Polyclonal and monoclonal antibodies

Produce polyclonal and monoclonal antibodies to proteins of HIV, SIV, SHIV and related human and nonhuman primate lentiviruses and to relevant host humoral or cellular antigens.

a) Prepare and evaluate high titer monospecific polyclonal antisera directed against purified proteins. The specificities and titers of the antibodies shall be determined by assays approved by the Project Officer.

b) Produce and evaluate epitope-specific monoclonal antibodies.

c) Produce, propagate, and preserve hybridoma cell lines generating the monoclonal antibodies.

d) Produce monoclonal antibodies by growing hybridomas. The cell lines, antisera, ascites fluid, culture fluid, or immunoglobulin fractions shall be produced as designated by the Project Officer.

C. Analyze acquired or generated reagents for purity and integrity, and provide quality assurance appropriate for the reagent type.

1. Provide quality control for all reagents (e.g., cloning and expression vectors, gene products, monoclonal antibodies, viral stocks, and topical microbicides).

The Contractor is responsible for independently characterizing and assuring the quality of each lot of reagent or virus whether produced by the Contractor or obtained by the Contractor from another source. The Contractor shall provide to the Project Officer a Data Sheet containing this information upon completion of each analysis.

2. Characterize each production lot of antibody

Each production lot of antibody is to be characterized as to immunoglobulin subtype, antigenic specificity by western blot or similar assay (including extent of cross-reactivity with a panel of viruses), titer in standard ELISA assay (or other assay approved by the Project Officer), freedom from human and rodent pathogens and (in the case of purified immunoglobulin) protein concentration. Provide to the Project Officer a data sheet containing this information following completion of analysis of each production lot.

3. Verify the identity of gene sequences from received or cloned DNA by PCR techniques as requested by the Project Officer.

D. Prepare, produce, and purify soluble proteins in large-scale production lots under Good Laboratory Practices (GLP).

1. Produce and purify proteins which are expressed and retain biological activity in assays specified by the Project Officer. The expression vectors shall be prepared by the Contractor or supplied by the Project Officer.

a) Purify gene products obtained under paragraph B above, or prepare and purify fragments of them, and/or modify them by enzymatic treatment or chemical attachment (such as with synthetic peptides, fatty acids, or other moieties).

b) Reclone, subclone, or otherwise modify vector constructs provided by the Project Officer for production of HIV, SIV, or SHIV gene products including those cloned from HIV-1 field isolates. Use such altered constructs to produce HIV, SIV, or SHIV gene products.

E. Maintain an electronic inventory of reagent stocks and a database of all reagent analysis results.

1. Provide Inventory and Database Management System

Maintain a computerized inventory and distribution database to track samples and activities under this contract. Whatever database tracking system is proposed, the Offeror must be willing to adopt the existing system under the current contract, or develop or provide a new system, either of which must guarantee the integrity and accessibility of the data in the current system.

a) Maintain documentation on file for all incoming and outgoing samples including condition of sample, temperature maintained in transit, method of processing, storage conditions and specific storage location.

b) Maintain a tracking system such that any sample or reagent can be traced from receipt through processing, storage, and distribution.

c) Provide monthly notification to the Project Officer of products or isolates received/produced the preceeding month.

F. Provide for appropriate receipt, storage, maintenance, and distribution of all reagents in stock. Maintain inventories of produced or procured reagents (e.g., gene products, monoclonal antibodies, and virus stocks). Ship quantities specified by the Project Officer.

1. Inventory Maintenance and Distribution of Reagents.

Use shipping conditions appropriate to preserving activity of any reagent and that comply with domestic and international postal regulations and pertinent regulation by international, national and local entities for the transportation of hazardous materials, including infectious substances. Commercial carriers (airlines) and couriers (e.g., FedEx, DHL, others) can also impose conditions to their acceptance of packages for transports. Within the United States, hazardous materials transportation is regulated by Title 49 of the Code of Federal Regulations (49-CFR). For the global shipping community, the International Air Transport Association (IATA) publishes the IATA Dangerous Goods Regulations (DGR) manual. This manual is updated annually to ensure and provide instructions for compliance with the UN Recommendations. A copy of the international Dangerous Goods Regulations can be found at http://www.iata.org/cargo/dg/index.htm.

2. Provide facilities and equipment to receive, store and manipulate biohazardous materials (Biosafety Level 2/3 containment) and maintain their viability.

The facilities must provide aseptic and/or sterile conditions as appropriate. Maintain appropriate storage and inventory control of reagents produced under performance of this contract and ship reagents to investigators only as designated by the Project Officer. The Contractor shall:

a) Develop Material Transfer Agreements (MTAs) for distribution of reagents and virus isolates and stocks to DAIDS-supported investigators.

b) Obtain the appropriate licenses and permits required by Federal and State authorities for receipt and storage of the materials produced under this contract. Additionally, the Contractor shall obtain the appropriate interstate, intrastate and foreign shipping licenses and permits for transporting biologicals and hazardous substances.

c) Pick up incoming shipments from a specific airport or other contract site and coordinate such deliveries to minimize inadvertent storage under sub-optimal conditions and attendant degradation of reagent condition.

d) As may be requested with all reagents developed in this contract, deposit, as specified by or as designated by the Project Officer, appropriate quantities of characterized gene product or monoclonal antibody with the NIH AIDS Research and Reference Reagent Program repository.

e) Provide for appropriate storage of all reagents, especially for clones, proteins, virus stocks, and antisera at 18^0C to 22^0C, 2^0C to 8^0C, -10^0C to 20^0C, and -70^0C to -90^0C, respectively, in vapor phase/liquid nitrogen conditions and all other items necessary for appropriate storage of biological reagents with requisite monitoring of storage conditions to guarantee continuous proper storage.

f) Provide protective garments, equipment, and sufficient monitoring to assure safe handling of potentially hazardous materials. Specifically, the Contractor shall comply with all applicable health and safety regulations while conducting the work set forth herein.

g) Conduct work under this contract in accordance with all applicable Federal, state and local laws, codes, ordinances and regulations, including obtaining Institutional Animal Care and Use Committee (IACUC) certification if reagent production or other activities in the Contractor's laboratory requires the use of animals to complete the project. Work under this contract must be in compliance with the following basic references and other related modifications by the Public Health Service:

(i) "Biosafety in Microbiological and Biomedical Laboratories," U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, and National Institutes of Health, HHS Pub. No. (NIH) 88-8395 published by the U.S. government Printing office, second edition, May 1988, stock number 17-40508-3.

(ii) "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Post-Exposure Prophylaxis," Vol. 50, No. RR11, June 29, 2001; http://www.cdc.gov/mmwr/PDF/RR/RR5011.pdf; updates and consolidates all previous U.S. Public Health Service recommendations for the management of health-care personnel (HCP) who have occupational exposure to blood and other body fluids that might contain these agents.

(iii) "Agent Summary Statement for Human Immunodeficiency Viruses (HIVs) Including HTLV-III, LAV, HIV-1, and HIV-2" and "Occupationally Acquired Human Immunodeficiency Virus Infections in Laboratories Producing Virus Concentrates in Large Quantities: Conclusions and Recommendations of an Expert Team Convened by the Director of the National Institutes of Health (NIH) Reported by Division of Safety, National Institutes of Health," Morbidity and Mortality Weekly Report, Vol. 37, No. SU-04, April 1, 1988.

(iv) “Perspectives in Disease Prevention and Health Promotion Guidelines to Prevent Simian Immunodeficiency Virus Infection in Laboratory Workers and Animal Handlers”, Morbidity and Mortality Weekly Report, Vol. 37, No. 45, November 18, 1988.

G. Meet with the Project Officer, other members of DAIDS, and investigators within the other DAIDS-supported AIDS vaccine development programs (as stated in paragraph A above).

1. Participate in regular meetings (or conference calls) with the Project Officer and other members of DAIDS at least once per quarter year.

2. Attend DAIDS, NIAID-sponsored meetings. Attend meetings as often as three times per year with the Project Officer and other staff of the Vaccine and Prevention Research Program (VPRP), DAIDS, NIAID.

3. Obtain clearances for presentation of data.

   Provide advance copies of draft manuscripts (including abstracts and public presentations) resulting from data generated under this contract to the Project Officer and obtain clearance in writing before submitting for publication or presentation. Support from the Government contract shall be acknowledged in all abstracts, presentations, and publications, for example, “this work was supported by the NIAID contract number N01-AI-12345”. Approximately one month must be allowed for clearances by NIAID after receipt.

H. Provide for Orderly Transition to Successor Contractor.

By the end of the fourth year of this contract provide a transition plan and implement an orderly transition of data, reagents, all Government Furnished Property (GFP) and materials, and specimens to a successor Contractor or to the Government, subject to Project Officer approval. Shall deliver, if requested by the Project Officer and by the completion date of the contract, the following items: original data, reagents, stored specimens, virus stocks, and any necessary information related thereto, and an inventory of GFP.

[END OF STATEMENT OF WORK]

Notes To Offerors
Reagent Resource Support For AIDS Vaccine Development
DAIDS-03-01

NOTE #1 TO OFFEROR:

Personnel: The Offeror should describe in detail the responsibilities and level of effort of all proposed personnel who will be assigned to the contract. Documentation should also be provided on the qualifications, related experience, education, competence, and availability of the Principal Investigator and Technical and Administrative Support Staff; the extent to which outside consultants shall be used as well as assurances of their availability; and the percentage of time each staff member (including proposed subcontractors or consultants) will contribute to the project. Resumes, endorsements, and explanations of previous efforts should clearly demonstrate relevant training, experience, and specific accomplishments related to the specific tasks of this contract.

Administration/Management/Quality Control: The Offeror should describe an administrative framework showing clear lines of authority and a detailed work plan showing proposed time schedules for achieving contract objectives and maintaining quality control over the implementation and operation of the contract.

Summary of Related Activities: Documentation should include all previous and current projects of a similar nature, including the contract number or grant number, the sponsoring agency, the Project Officer, and a brief description of the project. **The form for submitting this information is accessible from the listing in SECTION J – ATTACHMENTS of this RFP.**

Subcontracting: If a subcontractor is proposed, similar technical information should be provided as part of the Technical Proposal as that required by the prime Offeror; i.e., technical approach, methods, experience, personnel qualifications and specific responsibilities, staff availability, facilities, resources, etc. Cost details should also be provided by the proposed subcontractor.

Facility Floor Plan/Equipment: The Offeror should include in the Technical Proposal a floor plan of the proposed facilities and a list of equipment to be dedicated to the project. Government furnished property (GFP) currently held by the incumbent contractor includes: a camera, an HPLC system, a densitometer, a centrifuge, a microplate reader, two printers, a voltage safeguard, a thermal cycler, a shaker, MacVector software, a refrigerated centrifuge, a Vacuset Vacubottle, a power supply, a gel box, a centrifuge rotor and bucket set, a freezer (Revco), a C02 incubator, a safety hood, three LN2 storage tanks with alarms, an invert microscope and a computer. All GFP currently held by the incumbent will be transferred to the successful Offeror. **Documentation of Biosafety Level 2/3 facilities should be provided.**

Biosafety Training: The Offeror must include in the Technical Proposal documentation of ongoing programs and plans for programs for: adequate training of personnel handling infectious agents including HIV and opportunistic pathogens associated with HIV infection, decontamination procedures, accident procedures, and monitoring for infection, as well as the ability to identify safety standards applicable to particular reagents likely to be acquired.

Conflicts of Interest: If the Offeror is a commercial firm selling or distributing AIDS-related reagents or products, the Offeror must address in the Technical Proposal how potential conflicts of interest will be resolved.

NOTE #2 TO OFFEROR (see paragraph A.): For purposes of preparing a budget, the Offeror should assume that at least eight individual viral gene products, four of which will be env gene products will be required per year. Examples of sources of such gene products are Althea Technologies, Inc. (San Diego, CA), AnaSpec, Inc. (San Jose, CA), Peptide Technologies Corporation (Gaithersburg, MD), Protein Sciences Corporation (Meriden, CT), and Therion Biologics Corporation (Cambridge, MA).

NOTE #3 TO OFFEROR (see paragraph A.): For purposes of preparing a budget, the Offeror should anticipate receiving three adjuvants per year for immunogenicity testing and two vaccine/adjuvant formulations per year for safety and stability testing.

NOTE #4 TO OFFEROR (see paragraph B.): For purposes of preparing a budget, the Offeror should anticipate receiving 5 HIV-1 field isolates per year for expansion to yield 30 ml of high-titer culture fluid per isolate.

NOTE #5 TO OFFEROR (see paragraph B.2.): It is anticipated that these clones will be provided by the Project Officer as plasmids or recombinant virus.

NOTE #6 TO OFFEROR (see paragraph B.2.): It is anticipated that this task may require several approaches for successful completion such as PCR amplification, subcloning, sequencing, and synthesis of oligonucleotides, etc. The technical proposal should describe in detail strategies for cloning assuming that DNA or viral isolates of interest will be provided by the Project Officer. Potential technical difficulties and alternative strategies should be discussed.

NOTE #7 TO OFFEROR (see paragraph B.3): At the present time, the Government does not know which expression vectors or the exact number of cloned genes that will be required during the term of this contract. However, a full range of capabilities is likely to be required. Therefore, for the purposes of technical evaluation, the Offeror must describe at least 3 expression systems available (one prokaryotic, one yeast or baculovirus, and one mammalian cell line), the Offeror's experience with each, and the technical approach for utilization of each. For the purpose of preparing a budget, the Offeror should assume that 2 genes per year will need to be cloned into expression systems, that the gene products will be produced and purified in small quantity (0.5 - 5 mg), and confirmed as the specific gene product with assays to be supplied by the Project Officer. The Offeror should further assume that one gene per year will be expressed in a baculovirus system and that one gene per year will be expressed in a mammalian system.

NOTE #8 TO OFFEROR (see paragraph B.4.): At the present time, the Government does not know the exact quantities or types of antibodies that will be required. For purposes of preparing a budget, the Offeror should assume that high titered rabbit polyclonal antiserum (100 milliliters each) will be prepared against 2 purified proteins per year.

The Offeror should assume that 2 hybridoma cell lines producing monoclonal antibodies to 5 distinct epitopes will be prepared per year from antigens produced by the Contractor or provided by the Project Officer. In addition, the Offeror should assume that antibodies from 10 hybridomas will be prepared as 3 ascites fluids (100 milliliters each), 3 culture fluids (100 milliliters each), and 3 purified immunoglobulin fractions (10 milligrams each). As part of the technical proposal, the Offeror must include a description of methods available for use in evaluating the specificity of all antibodies produced.

NOTE #9 TO OFFEROR (see paragraph C.3.): The Offeror should provide an example of the data sheet to be used for reporting the results of analyses.

NOTE #10 TO OFFEROR (see paragraph D.): An example of an expression system is vaccinia producing processed gag gene products (S.D. Gowda et al., J. Virol. 63:1451, 19891; J. Biol. Chem. 264:8459, 1989)]

NOTE #11 TO OFFEROR (see paragraph D.): At the present time, the Government does not know exactly what quantity of protein will be required. For purposes of preparing a budget, the Offeror should assume that approximately 50 - 200 mg of soluble forms of 2 proteins will be produced per year. Examples of proteins which may be expressed and purified during the first year are the following: SIV gp140 expressed in vaccinia and HIV-1 gp120 expressed in Chinese Hamster Ovary (CHO) cells.

NOTE #12 TO OFFEROR (see paragraph E.): The Offeror should include details of a proposed inventory tracking and notification mechanism/plan in the Technical Proposal. In this plan, the Offeror should describe a computerized mechanism for recording receipt and status and location of reagents, and a plan for a monthly notification to the Project Officer of products or isolates received/produced the preceding month.

NOTE #13 TO OFFEROR (see paragraph F.1.): The Offeror should estimate 60 shipments per year to Seattle, Washington and 10 shipments per year to Bangkok, Thailand for cost estimating purposes.

NOTE #14 TO OFFEROR (see paragraph F.2.): The Offeror should provide examples of the proposed Material Transfer Agreements.

NOTE #15 TO OFFEROR (see paragraph G.1.): For purposes of planning a budget, assume 3 trips a year for the Principal Investigator (or designate) and the Co-Investigator (or designate) to attend the meetings with the Project Officer which will be held in the Washington, D.C. metropolitan area.

NOTE #16 TO OFFEROR (see paragraph G.2.): At least one of the DAIDS, NIAID-sponsored meetings will be in the Washington, DC metropolitan area and will include representatives from the SVEUs and other VPRP-sponsored contractors and/or grantees. The Principal Investigator and the Co-Investigator may each attend one Scientific Meeting a year to present results obtained by this contract. The Project Officer must approve the Contractor's attendance and any presentation materials prior to their presentation.

Reporting Requirements
Reagent Resource Support For AIDS Vaccine Development
RFP DAIDS-03-01

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These shall be brief and factual and prepared in accordance with the following format:

A. Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below:

(1) Quarterly Progress Reports - On the 15th of each month following the end of each quarter, the Contractor shall submit three (3) copies of a quarterly progress report, two (2) copies to the Project Officer and one (1) original to the Contract Specialist, which consists of the following:

(a) A title page containing:

1) Contract number and title
2) Period of performance being reported
3) Contractor's name and address
4) Author(s)
5) Date of submission

(b) Reports will include, but are not limited to the following information:

1) Quality control data sheets, as described in paragraphs part C.1. of the Work Statement, including amounts of product on hand, for those well characterized reagents (e.g., viral gene products and monoclonal antibodies) which are available for distribution during each reporting period.
2) Status of work in progress for production of reagents which are not yet approved for distribution, including a summary list organized by type of reagent.
3) Description of any technical or performance problems encountered and corrective actions planned or taken. An explanation of any differences between planned and actual progress will be included.
4) Shipment records for gene products, antibodies, and/or other reagents, including:
   a) clear identification of item shipped
   b) quantity of item shipped
   c) date of shipment
   d) name and address of recipient
5) Any additional information requested within the Statement of Work, or as requested by the Project Officer.

(2) Annual Reports - The fourth Quarterly report shall represent the Annual Report and follow the format and time schedule for the Quarterly report. The Annual report shall summarize progress for the entire Contract year and be submitted on the 15th of the month following the end of the reporting period.

(3) Final Report - The Contractor shall submit three (3) copies of the final report documents, two (2) copies to the Project Officer and one (1) original to the Contract Specialist, that will summarize the results of the entire contract work for the period of performance covered. This report will be in sufficient detail to explain comprehensively the results achieved, and will be submitted no later than the completion date of the Contract.

The final report shall contain:

a. Title Page as described above in paragraph A.l.a.
b. Introduction covering the purpose and scope of the contract effort.
c. Description of the overall progress, plus a separate description of each task on which effort was expended during the period of performance. Descriptions will include pertinent data to present significant results achieved and a scientific evaluation of the data accrued under the contract.
d. A Summary of Salient Results (not to exceed 200 words) of salient results achieved during the performance of the contract.

B. Technical Report Distribution

In addition to the numbers of hard copies indicated below, one (1) electronic version of each technical report (Quarterly, Annual, and Final) shall be submitted to the indicated Addressee as well:

Type of Report	No. of Hard Copies	Addressee	Due Dates
Quarterly	2	Project Officer, VPRP, DAIDS, NIAID 6700B Rockledge Drive, Room 4104 Bethesda, MD 20892-7628 E-Mail:	15th of the month following end of each quarter. Not due when Annual and Final submitted.
Quarterly	1	Contract Specialist, CMB, NIAID 6700B Rockledge Drive, Room 2106 Bethesda, MD 20892-7612 E-Mail:	
Annual	2	Same as Project Officer above	15th of the month following each anniversary date of the Contract. Not due when Final submitted.
Annual	1	Same as Contracting Officer above	
Final	2	Same as Project Officer above	Due on/before completion date of the contract.
Final	1	Same as Contracting Officer above	

If the Contractor becomes unable to deliver the reports specified hereunder within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice (with justifications) of anticipated delays.

C. Other Deliverables

The Contractor, subject to Project Officer approval, shall deliver to the Government or its designee by the completion date of the Contract, the following items:

(1) All reagents, including (but not limited to) stored specimens, adjuvants, immunomodulators/delivery systems, antibodies, and microbicides, and including those received by the Contractor from the Project Officer or designated investigators;
(2) A computer-generated listing of accurate and updated information on the specimen and reagent inventories, including quality assurance/control activities of the Contractor, computerized data files, original data and any necessary information related thereto;
(3) The electronic file systems (inventory databases) as computer files with clear and concise documentation, and the entire existing database tracking system, it's accumulated data, including it's source code if applicable, and exclusive rights so that the integrity and accessibility of these data can be maintained upon transfer to the Government or its designee;
(4) Labeled and inventoried paper files, electronic media; and
(5) Government-owned equipment and property inventory.

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm

[Disregard SECTION I and J of this sample. Those SECTIONS have been incorporated as part of this RFP.]

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

BECAUSE THIS IS A STREAMLINED RFP, ARTICLES I.2. AND I.3., WHICH IDENTIFY ANY AUTHORIZED ADDITIONS, SUBSTITUTIONS AND/OR MODIFICATIONS TO THE GENERAL CLAUSES, WILL BE BASED ON THE TYPE OF CONTRACT/CONTRACTOR AND WILL BE DETERMINED DURING NEGOTIATIONS.

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this URL: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

FAR Clause No.	Date	Title
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Feb 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)

52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (NOTE: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Feb 1999	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	Feb 2002	Buy American Act - Balance of Payments Program – Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs

52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR Clause No.	Date	Title
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – Rev. 02/2002]

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)

HOW TO PREPARE AN ELECTRONIC PROPOSAL: (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: May 31, 2002] (Attached to this listing)

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

http://www.niaid.nih.gov/contract/ref.htm

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- **Technical Proposal Cover Sheet**
- **Technical Proposal Cost Information**
- **Summary of Related Activities**
- **Government Notice for Handling Proposals**

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- **NIH-2043, Proposal Summary and Data Record**
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Offeror's Points of Contact**

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Report of Government Owned, Contractor Held Property**
- **Disclosure of Lobbying Activities, OMB Form LLL**

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Listed below are delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals. *You are required to submit one original paper copy of your proposal along with the number of extra copies required below.*

ELECTRONIC SUBMISSION: In addition to the paper submission, you are required to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided below. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system. You must certify that both the original paper and electronic versions of the proposal are identical.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

Shipment and marking of paper copies shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFP NO. NIH-NIAID-DAIDS-03-01
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Technical Proposal: One (1) unbound signed original; One (1) electronic file and Five (5) unbound copies. Ten (10) copies of all material not available electronically (i.e. SOPs, Pertinent Manuals, Non-scannable Figures or Data, and Letters of Collaboration/Intent).

Business Proposal: One (1) unbound signed original; One (1) electronic file and Five (5) unbound copies.

C. PAPER COPIES and CD-Rom or ZipDisk to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Lois Eaton Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Lois Eaton Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 100 PAGES [INCLUDING: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.]. IT IS RECOMMENDED THAT YOU LIMIT ANY CVs TO NO MORE THAN 2-3 PAGES EACH. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

> **Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.**

ELECTRONIC SUBMISSION – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in this attachment and must be received on/before the closing date and time.

There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

SUBMISSION OF "PROPOSAL INTENT TO RESPOND SHEET":

Approximately TWO weeks prior to the due date of the proposals, all offerors who submitted a "Proposal Intent Response Sheet" will be provided with specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached "Proposal Intent Response Sheet" by the date provided on that Attachment.

CREATE ADOBE PDF ONLINE -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs $10/month or $100/year. Please link to the following URL for information:

https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE

LOG-IN / TRANSMISSION INSTRUCTIONS:

1. Log-in Site: https://apps.niaid.nih.gov/ecms/cmsproposal
2. Log-in Name: Will be provided by the Contract Specialist.
3. Log-in Password: Will be provided via telephone by the Contract Specialist after Log-in Name is provided.

4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.

   - You must have Explorer 3.1 or higher.
   - It is essential that you use antiviral software to scan all documents.
   - Click on "Sign On" and enter your log-in name and password.
   - Click on "Browse" to locate your saved files on your computer.
   - Click on "Upload Proposal" after you have located the correct file.
   - After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
   - If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
   - If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIDS-03-01
RFP Title: Reagent Resource Support for AIDS Vaccine Development

Please review the attached Request for Proposal. Furnish the information requested below and return this page by May 31, 2002. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):
_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
CMB, NIAID, NIH
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Lois Eaton
RFP-NIH-NIAID-DAIDS-03-01
FAX# (301) 402-0972 or (301) 480-5253
Email : le52u@nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

http://rcb.nci.nih.gov/forms/rcneg.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF THE PRIME BUSINESS PROPOSAL AND ANY SUBCONTRACTOR BUSINESS PROPOSALS.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Clause 52.215-1 (May 2001)]

(a) *Definitions*. As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"*In writing*", "writing", or "*written*" any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;
(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.* (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular

circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

b. **NOTICE OF SMALL BUSINESS SET-ASIDE**

(a) **General**. Bids or proposals under this procurement are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.

(b) **Definitions**. The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the criteria set forth in the regulations of the Small Business Administration (13 CFR 121.3-8). In addition to meeting these criteria, a manufacturer or a regular dealer submitting bids or proposals in his own name must agree to furnish in the performance of the contract end items manufactured or produced in the United States, its territories and possessions, Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia, by small business concerns. Provided, that this additional requirement does not apply in connection with construction or service contracts.

c. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 54171 .
(2) The small business size standard is 500 employees .

d. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that ONE AWARD(S) will be made from this solicitation and that the award(s) will be made on/about February 14, 2003.

It is anticipated that the award(s) from this solicitation will be a multiple-year, cost reimbursement, completion type contract with a period of performance of seven (7) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 101,920 total labor hours (7.0 FTEs) for the seven year period of performance. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

j. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

k. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Brenda J. Velez
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases, NIH
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA MD 20892-7612

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

l. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

m. **USE OF INTERNET WEB SITE ADDRESSES (URLs) IN PROPOSALS**

Unless otherwise specified or required in NIAID solicitations, internet Web Site addresses (URLs) may not be used to provide information necessary to the conduct of the review of the proposal. Direct access to an internet site by a Reviewer who is examining and reviewing the proposal on behalf of the NIAID could compromise their anonymity during the review process. If a URL contains information pertinent to the proposal content, the offeror must provide access to the website via a temporary website portal which allow reviewers the capability to view and interact with the site.

The proposal must clearly identify the URLs to be accessed and the procedure for accessing the temporary website portal. Access must not require the identity of the individual.

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement, completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled,

TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Care of Live Vertebrate Animals**

a. The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory

Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at http://ott.od.nih.gov/NewPages/64FR72090.pdf.

b. If an Animal Assurance is already in place, the offeror's proposal shall include:

-The Animal Welfare Assurance number.
-The date last certified by OLAW. (i.e. assurance letter from OLAW)
-Evidence of recent AAALAC Accreditation.

(10) **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf.

(11) **Privacy Act (Treatment of Proposal Information)**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(12) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is this Institute’s policy to conduct discussions with all offerors in the competitive range, the Institute reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The Institute reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet the Institute's requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily and FedBizOpps.

(13) **Reimbursement of Costs for Independent Research and Development Projects** (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(14) **Salary Rate Limitation in Fiscal Year 2002** **

Offerors are advised that pursuant to P.L. 107-116, no NIH Fiscal Year 2002 (October 1, 2001 - September 30, 2002) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 107-116 applies only to Fiscal Year 2002 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 107-116 states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I."

Information regarding the FY-2002 rate can be found at: http://www.opm.gov/oca/02tables/ex.pdf

(15) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(16) **Past Performance Information**

a) Offerors shall submit the following information as part of their BUSINESS proposal.

A list of the last five (5) contracts completed during the past three (3) years and the last three (3) contracts awarded currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as any subcontract over $550,000.

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(17) **Electronic and Information Technology Accessibility**

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

1. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

2. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov.

(18) **Solicitation Provisions Incorporated by Reference**, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

b) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

c) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

f) Facilities

The Offeror should include in the Technical Proposal a floor plan of the proposed facilities and a list of equipment to be dedicated to the project. Government furnished property (GFP) currently held by the incumbent contractor includes: a camera, an HPLC system, a densitometer, a centrifuge, a microplate reader, two printers, a voltage safeguard, a thermal cycler, a shaker, MacVector software, a refrigerated centrifuge, a Vacuset Vacubottle, a power supply, a gel box, a centrifuge rotor and bucket set, a freezer (Revco), a C02 incubator, a safety hood, three LN2 storage tanks with alarms, an invert microscope and a computer. All GFP currently held by the incumbent will be transferred to the successful Offeror. **Documentation of Biosafety Level 2/3 facilities should be provided.**

c. **BUSINESS PROPOSAL INSTRUCTIONS**

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Information Other than Cost or Pricing Data

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.

b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**

   Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

   If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

   Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

    List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: http://rcb.nci.nih.gov/forms/cpi.htm

(3) Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(4) Other Administrative Data

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

e) **Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)**

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(5) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm

(6) Proposer's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(7) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(8) Travel Costs/Travel Policy

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are [significantly more important than cost or price/approximately equal to cost or price/significantly less important than cost or price]. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. **PAST PERFORMANCE FACTOR**

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be the product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers all available and relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

The following rating method shall be used in the evaluation of past performance information:

+2 **Excellent** - Based on the offeror's performance record, no doubt exists that the offeror will successfully perform the required effort. Sources of information are consistently firm in stating that the offeror's performance was superior and that they would unhesitatingly do business with the offeror again.

+1 **Good** - Based on the offeror's performance record, little doubt exists that the offeror will successfully perform the required effort. Sources of information state that the offeror's performance was good, better than average, etc., and that they would do business with the offeror again.

None - No past performance history identifiable.

-1 **Marginal** - Based on the offeror's performance record, some doubt exists that the offeror will successfully perform the required effort. Sources of information make unfavorable reports about the offeror's performance and express concern about doing business with the offeror again.

-2 **Poor** - Based on the offeror's performance record, serious doubt exists that the offeror will successfully perform the required effort. Sources of information consistently stated that the offeror's performance was entirely unsatisfactory and that they would not do business with the offeror again.

The past performance subfactors are listed below in order of relative importance. These sub-factors will be used to evaluate the quality of past performance.

Past Performance Subfactors

Record of conforming to specifications and to standards of good workmanship

Record of forecasting and controlling costs under cost-reimbursement contracts

Adherence to contract schedules, including the administrative aspects of performance

Reputation for reasonable and cooperative behavior and commitment to customer satisfaction

Business-like concern for the interest of the Customer

1. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

CRITERA **WEIGHT**

A. TECHNICAL APPROACH **(45 Points)**

Adequacy of the proposed plans for acquisition, preparation, storage, analysis, quality assurance, inventory maintenance and distribution of viral gene products, adjuvants, microbicides, and all other reagents developed under this contract. Address the feasibility and/or practicality of successfully accomplishing the requirements set forth below, including a statement/discussion of anticipated major difficulties or problem areas and recommended approaches for their resolution. Include the availability of required research, tests, and other equipment or facilities. Requirements of this contract will include, but not be limited to:

A.1. protein purification and analysis, particularly in the context of viral gene products; designing and performing protocols demonstrating that a product lot contains a particular gene product, assessing its identity, integrity, and purity (e.g., identifying nature and amount of any degradation products), and reliably quantifying its amount and availability;

A.2. producing, receiving, or procuring novel vaccine DNA preparations (e.g., recombinant plasmids) and vaccine adjuvants, immunomodulators, and vaccine delivery systems primarily under current Good Laboratory Practice (cGLP) standards for both nonhuman primate and clinical studies under Good Manufacturing Practice (cGMP) standards, and evaluating these reagents in standardized quality control and quality assurance tests for identity, size, appearance, stability, purity, and sterility; acquiring reagents used to evaluate AIDS vaccine safety and immunogenicity (which may include, but are not limited to, reagents for use in lymphoproliferation, ELISPOT, and intracellular cytokine assays, CTL activity assessments, and antibody binding/virus neutralizing assays), reagents needed for evaluation of the safety and potential efficacy of topical microbicides, and the reagents and assays for evaluating the biological effects of these prevention formulations; generating or acquiring in sufficient quantities custom reagents not otherwise available for AIDS vaccine and topical microbicide research to support uniform and comparable testing of these products including preparing and/or producing soluble proteins, expression vectors, and gene products (including experimental AIDS vaccines) under cGLP or cGMP as appropriate for their intended use, and preparing and/or producing these in large-scale production lots;

A.3. proposing adequate plans for monoclonal/polyclonal antibody production, analysis, storage, quality assurance, inventory maintenance and distribution, including protocols for antibody purification, sub-class typing, assessing reactivity with viral proteins and cross-reactivity with a variety of relevant viral isolates, maintaining "clean" animals free of rodent and human pathogens, testing for rodent and human pathogens described in the Work Statement, for ascites fluid production, and for tissue culture production of antibodies.

B. PERSONNEL **(40 Points)**

B.1. Other Professional Staff **(30 Points)**

-- documented related experience and capability of the assigned personnel. Documented training, experience and availability of the proposed other professionals, research, technical, management, and support staff. Documented capability to perform their roles in the proposed work. Expertise in similar projects. The logistical adequacy of the staffing plan for the conduct of the project, including the responsibilities and time commitment of the professional and technical staff. Competency and experience of the proposed staff in the skills required in the Statement of Work, and their resumes (and those of subcontractors and/or consultants) reflect not only academic qualifications, but length and variety of experience in similar tasks and clearly demonstrate relevant training and experience. Specifically:

-- experience and capability of personnel for protein purification and analysis, particularly in the context of viral gene products;

-- experience and capability of personnel for monoclonal/polyclonal antibody production and analysis and in lymphocyte culture for adjuvant evaluations;

-- experience and capability of personnel for manipulation of recombinant vaccine vector constructs including recombinant plasmid DNAs, vaccinia constructs, avipox constructs, and other potential vaccine vectors as designated by the Project Officer; and

-- experience and capability of personnel for manipulation of topical microbicides and/or for other reagents with similar properties.

-- Subcontractors: document training, related experience and availability of any proposed subcontractor(s), their documented capability to perform the proposed work, and expertise in similar projects. The logistical plan for use of the subcontractor(s) in the conduct of the project, including the time commitments of the professional and technical staff. Quality and feasibility of the plan to identify the need to add, replace, or remove the subcontractor's scientific staff, dependent on the progress or change in scientific direction. Plans for evaluating the performance of subcontractors.

B.2. Principal Investigator **(10 Points)**

-- Education and training of proposed Principal Investigator, and documented recent experience in administering a project of similar content and complexity. Documented training, relevant scientific experience, administrative leadership, and experience in project management. Availability of a Principal Investigator. The administrative framework, indicating clear lines of authority and responsibility for the project's management.

-- The overall plan of the Principal Investigator and the surrounding leadership to successfully manage a project of this nature. Managerial ability to achieve delivery or performance requirements as demonstrated by the proposed use of management and other resources, and to successfully manage the project, including subcontractor(s) and/or consultant efforts, if applicable, as evidenced by the management plan and demonstrated by previous experience.

C. FACILITIES AND ORGANIZATION **(15 Points)**

1. Adequacy, safety, and availability of facilities and equipment for performing all operations of production (cGLP, cGMP, and otherwise), analysis, storage, and shipping of reagents produced under this contract. The Offeror must provide:

    a. a detailed laboratory layout, including designation of areas for work with biohazardous materials, including required areas for Biosafety Level 2/3 containment;

    b. information regarding ownership/lease of the facility, including its demonstrated availability for the duration of the proposed contract;

    c. a plan for compliance with all safety guidelines and regulations, including training and monitoring of personnel for exposure to infectious and hazardous materials (to include SOPs for work with viruses and other biohazardous materials.

2. Adequacy of organizational structure including lines of authority to provide for the efficient interaction and communication, and task assignments between personnel assigned to individual components or functions of the contract.

3. Adequacy of plans for the orderly transition to a successor Contractor. To be developed by the end of the sixth year of this contract and will provide the orderly transition of data, reagents, all government-owned equipment and materials, and specimens to a successor Contractor or to the Government.

TOTAL POINTS **(100 Points)**